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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/087,929

03/01/2002

Clarence N. Ahlem

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10/04/2006

HOLLIS-EDEN PHARMACEUTICALS, INC.
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EXAMINER

KENNEDY, SHARON E

ART UNIT

PAPER NUMBER

1615

DATE MAILED: 10/04/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/087,929	AHLEM ET AL.	
	Examiner	Art Unit	
	Sharon E. Kennedy	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 16 June 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-4,6-16 and 46-61 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-4,6-16 and 46-61 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>02/02/2006</u> | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action or the MPEP.

Effective Filing Date

The examiner takes the position that the effective filing date for claims directed to a method of treating a blood cell deficiency is March 29, 2001. The method is disclosed in applicant's parent application 09/820,483, filed March 29, 2001, but not in any earlier application.

Double Patenting

Claims 1-4, 6-14, 46-61 of this application conflict with claims 38, 39, 58, 59 of Application No. 10/651,515. 37 CFR 1.78(b) provides that when two or more applications filed by the same applicant contain conflicting claims, elimination of such claims from all but one application may be required in the absence of good and sufficient reason for their retention during pendency in more than one application. Applicant is required to either cancel the conflicting claims from all but one application or maintain a clear line of demarcation between the applications. See MPEP § 822.

This applicant is broadly directed to a "method to treat a blood cell deficiency." Claim 39 of the '515 applicant is directed to a hemorrhage. Accordingly, this rejection is proper. Regarding claim 59, it is well known that sepsis causes neutropenia.

Claims 1-4, 6-14, 46-61 of this application conflict with claims 1-25, 27 of Application No. 10/728,400. 37 CFR 1.78(b) provides that when two or more applications filed by the same applicant contain conflicting claims, elimination of such

claims from all but one application may be required in the absence of good and sufficient reason for their retention during pendency in more than one application. Applicant is required to either cancel the conflicting claims from all but one application or maintain a clear line of demarcation between the applications. See MPEP § 822.

Claim Rejections - 35 USC § 112

Claims 1-4, 6-14, 46-61 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The claims are confusing because R^4 is - $N(R^{PR})_2$, - NHR^{PR} . However, in view that RPR can be -H, it is unclear what is meant by the R^4 limitation. In other words, there is no difference between formulas - $N(R^{PR})_2$, and - NHR^{PR} . Accordingly, the claims are confusing.

Claims 1-4, 6-14, 46-61 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. Note is made of applicant's affidavits, which has been carefully studied. However, the small number of tested compounds is insufficient to cover the scope of the claimed compounds. Applicant's broadly drafted compound includes all of the compounds recited in Class 552/522-653. The examiner admits that the number of subclasses encompassing a compound is not an approved test of enablement, however, it provides a concrete example of the breadth of the compound.

Claim Rejections - 35 USC § 102

Claims 1-4, 6-13, 46-53, 55, 56 are rejected under 35 U.S.C. 102(e) as being clearly anticipated by Savage et al., US 6,350,738. Note column 12, line 2, which discloses that the Savage compounds are useful for treating the side effects of sepsis such as neutropenia, leucopenia, etc. Regarding the compound, note column 1, formula I, R₁₇ can be amino alkyl. Regarding claims 3, 4, see column 1, line 66, regarding R_{1-4,6,7,11,12,15,16} and "hydroxyl" in column 2, line 1. Regarding claim 13, note that renal failure is contemplated. See column 12, line 16.

Claim Rejections - 35 USC § 103

Claims 14, 54, 57-61 are rejected under 35 U.S.C. 103(a) as being unpatentable over Savage '738. Claim 14 recites the ordinary steps of obtaining blood and measuring white, red cell counts, etc. One of ordinary skill in the art such as a medical professional, e.g. nurse, understands that these steps are normal protocol and such would be obvious to one of ordinary skill in the art. Regarding claims 54, 57-61, although the Savage invention is directed to the treatment/prevention of sepsis, it is well known in the art that tumor treatments such as radiation or chemotherapy will give rise to a higher incidence of sepsis. Accordingly, the examiner takes the position that the means by which the blood cell count is lowered is irrelevant to the method of treating neutropenia, etc. Note is made that claim 52 (not included in this rejection but still relevant) is directed to a method of treating a mammal who may be subject to developing neutropenia. The examiner takes the position that this broadly includes treating patients with sepsis.

Conclusion

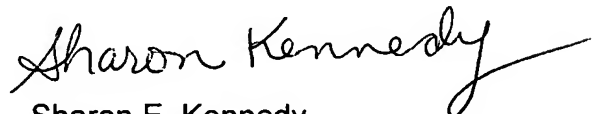
In view of the new art rejections, this office action is being made non-final.

Contact Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sharon E. Kennedy whose telephone number is 571/272-4948. The examiner can normally be reached on Monday-Thursday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward, can be reached on 571/272-8373.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


Sharon E. Kennedy
Primary Examiner
Art Unit 1615